UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Subcategory No. 06-11337-PBS
	)	(Docket # 6316)
U.S. ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc. No. 07-CV-11618-PBS	)	Hon. Patti B. Saris

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S
MOTION FOR PARTIAL SUMMARY JUDGMENT

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I. INTRODUCTION

Ven-A-Care of the Florida Keys, Inc. ("VAC") respectfully submits this brief in support of its motion for partial summary judgment. Abbott's conduct herein basically mimicked that of other pharmaceutical companies previously found liable for their drug pricing fraud. There is little factual disagreement about the fraud VAC alleges against Abbott, much of which is apparent from irrefutable data and Abbott corporate testimony. For example, there is no dispute that Abbott reported list prices for its erythromycin ("Ery") products that were unmoored to its actual transaction prices and that those prices were several times the actual sales prices for the Abbott drugs at issue in this case. *See* Plaintiff's Local Rule 56.1 Statement of Undisputed Material Facts (hereafter "VAC-ERY-SF") ¶¶ 7-9. The record also reveals that Abbott employees knew that these list prices were used by publishers to calculate AWPs and that those AWPs were then used by state and federal government agencies to set reimbursement levels for Abbott's drugs. (VAC-ERY-SF ¶¶ 15-16, 22-31, 42, 134). Further, Abbott employees acknowledged that the price reporting practices for the Ery products differed from the Pharmaceutical Products Division's normal practices, reflecting a deliberate scheme to promote sales of these generic products through enhanced third party reimbursements, including by Medicaid. (VAC-ERY-SF ¶¶ 6-7, 11).

Notably, Abbott tacitly acknowledged the fraudulent nature of its price reporting conduct in April 2001 by drastically reducing its reported prices for many of the generic drugs sold through its Hospital Products Division, in part in response to investigations by the United States Department of Justice and Congressional investigators. (US-A-SF ¶¶ 56-58, 60-64)[1]; (VAC-

[1] Because much of the evidentiary record applicable to these claims has already been set out at length in the briefing on the motions for summary judgment in the United States' Abbott action, VAC attempts to avoid duplication by cross-referencing those filings wherever

ERY-SF ¶11 ("The wide disparity in catalog prices and average market price … is not supported by sufficient financial or market factors to survive scrutiny of public opinion")). For the Ery products, however, Abbott continued to report inflated prices and cause injury to Medicaid – despite expressly recognizing and considering the "exposure" caused by its high list prices for these PPD products. (VAC-ERY-SF ¶ 12) Parallel to the United States' Motion for Partial Summary Judgment Against Abbott, and its Motion for Summary Judgment as to Certain of Abbott's Affirmative Defenses, VAC hereby moves for Partial Summary Judgment on liability, as well as for summary judgment as to certain of Abbott's Affirmative Defenses.[2]

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appropriate. Accordingly, references are made herein to the Lavine Declarations (Docket Nos. 6302, 6305, 6308, 6312 and 6323), Henderson Declaration (Docket No. 6310) and exhibits thereto, the Declaration of Mark G. Duggan, Ph.D. (Exhibit 41 to Henderson Declaration (Docket 6310) in Support of the United States' Motion for Partial Summary Judgment (Docket No. 6318), and to the United States' Local Rule 56.1 Statements of Undisputed Facts (Docket Nos. 6316 and 6321) (referenced, as in the federal cases, as US-A-SF for the Statement of Facts pertaining to Abbott, and US-C-SF, for the United States Common Statement of Facts), all of which were filed by the United States in connection with the Motion for Summary Judgment against Abbott. This case and this motion simply address some additional Abbott products that were marketed by a different Abbott division and that were not intervened on by the United States. Since these drugs were not reimbursed by the Medicare program, this case involves only claims made on Medicaid.

[2] VAC moves for summary judgment as to the following Affirmative Defenses: Good faith, established industry practice (Seventh Affirmative Defense); laches, estoppel and waiver (Eleventh); Abbott's actions were not proximate cause of any injury (Thirteenth); Abbott did not make any false statements to the plaintiff, or if false or misleading, Abbott had no reasonable grounds to believe and did not believe that the statements were false or misleading (Fifteenth); *in pari delicto* or unclean hands (Nineteenth); Plaintiff's failure to follow state and federal regulatory obligation to set reimbursement rate at appropriate Estimated Acquisition Cost (Twentieth); failure to mitigate damages, plaintiff would be unjustly enriched, consent or ratification to extent government paid for drug products after initial complaint filing in 1998 (Twenty-fifth); Abbott's conduct was not material to any alleged injuries suffered by plaintiff (Thirty-First); no reliance by United States or states (Thirty-Second); plaintiff knew and was aware the AWP was not an actual average of wholesale prices or the actual acquisition cost of drugs (Thirty-Sixth); and contributory or comparative fault because of plaintiff's own conduct or failures (Thirty-Ninth).

II. SUMMARY OF UNDISPUTED FACTS

A. Overview of Abbott, Abbott Products and Abbott Spreads

Abbott manufactures and sells drugs, medical products and devices. The Erythromycin ("Ery") products at issue herein were sold by Abbott's Pharmaceutical Products Division ("PPD"). (VAC-ERY-SF ¶¶ 1-3). Most products sold through PPD were brand drugs, for which reasonably accurate prices were reported. (VAC-ERY-SF ¶ 6). The Ery products, however, were handled differently, as explained below. Additionally, from 1991 until after 2001, Abbott operated a division it called the Hospital Products Division (Abbott HPD), which sold the drug products that are at issue in the lawsuit being jointly litigated by the United States and Ven-A-Care: Vancomycin; Dextrose; Saline; and Sterile Water. (US-A-SF ¶¶ 2-4) The United States is seeking partial summary judgment in that case also.

B. Abbott's Price Reporting Practices

Since 1991, Abbott has regularly reported list prices to the major drug pricing compendia: First Databank, Red Book, and Medispan. (US-A-SF ¶ 83); (VAC-ERY-SF ¶ 6). During the 1990's, Abbott PPD reported AWPs to the compendia (VAC-ERY-SF ¶ 6), and thereafter Abbott was aware that the pricing compendia calculated and published AWPs for Abbott's products based on a set markup over the prices Abbott reported. *Id*. The Publishers determined Abbott's AWP by applying an 18.75 percent mark-up to the list price, or 25% above WAC. (US-A-SF ¶ 88); (VAC-ERY-SF ¶¶ 6, 14). Abbott communicated routinely with the Publishers regarding its reported prices. (US-A-SF ¶ 83); (VAC-ERY-SF ¶ 6). Those communications included verifying the accuracy of its prices as published, when requested from at least one Publisher. (US-A-SF ¶ 36); (VAC-ERY-SF ¶ 6). In addition, Abbott understood the relationship between reported list prices and AWPs published by the Publishers. (US-A-SF

¶¶ 31, 36, 83); (VAC-ERY-SF ¶ 14). As one employee succinctly described, "AWP is a function of list." (US-A-SF ¶ 33).

The published AWPs for Abbott's Ery products were inflated because Abbott reported inflated list prices to price reporting compendia or publishers. The majority of drugs sold through PPD were branded drugs. (VAC-ERY-SF ¶ 4). For those drugs sold by PPD, Abbott reported a list price or WAC that accurately reflected the price at which it invoiced wholesalers. Specifically, the prices that Abbott PPD reported to the three publishers for nearly all of its products used a figure that was only five percent higher than PPD's wholesale acquisition cost (WAC) (net of chargebacks and discounts) on the products. (US-A-SF ¶ 68, 70); (VAC-ERY-SF ¶ 6). From this price, Abbott was aware that FDB calculated an AWP at 125% of the reported WAC. (VAC-ERY-SF ¶ 14). For most of the PPD products, therefore, Abbott's reported prices resulted in a published AWP that reasonably reflected the prices at which its drugs were actually sold.

Certain drugs sold by PPD, however, such as erythromycin and gengraf, were multi-source drugs for which Abbott realized that the market conditions were different. As with Abbott's HPD drugs, the multi-source drugs sold by PPD competed in the marketplace based primarily on price and reimbursement spread. (*See* VAC-ERY-SF ¶¶ 15-16, 32-35, 43). For these drugs, Abbott PPD deviated from its usual price reporting practices and reported as a WAC a price that did not reflect the price at which it invoiced the products to wholesalers. (VAC-ERY-SF ¶¶ 7-8, 12). Instead, Abbott reported a WAC price that did not meet its own definition of WAC – price to wholesalers – and did not reflect in any fashion the prices at which its products were sold. (VAC-ERY-SF ¶¶ 7, 9, 12).

Notably, the Abbott employees responsible for reporting prices to the pricing compendia for PPD drugs, including the Ery products, had access to the bid schedule pricing that was used to invoice wholesalers. (VAC-ERY-SF ¶ 10). Abbott calculated its average sales prices on at least a monthly basis, based on WAC sales less rebates, discounts, return goods allowance and any other billing adjustments. (VAC-ERY-SF ¶ 21). Joe Fiske, Abbott's corporate representative regarding PPD pricing, could not explain why the lower prices at which wholesalers were invoiced for Ery products were not the WAC prices that were reported to the pricing compendia, other than to say that the pricing compendia expected WAC and list pricing from manufacturers. (VAC-ERY-SF ¶ 12).

In fact, the Ery products were sold at what Abbott called "base deal" prices, which were not reported to the pricing compendia or Medicaid programs. (VAC-ERY-SF ¶¶ 7-8, 17-20). Indeed, Abbott PPD employees testified that the base deal prices were considered confidential and would not have been disclosed to the pricing compendia. (VAC-ERY-SF ¶ 8). The base deal prices were widely available to wholesalers and purchasers and were a fraction of the prices that Abbott reported as WACs. (VAC-ERY-SF ¶¶ 17, 18). Base deal prices were sometimes limited to wholesalers who met a certain threshold volume of sales, and then the price was extended throughout the year, and at other times base deal prices were invoiced without regard to volume. *Id*. Sales to customers above those base deal prices were "rare." *Id*. Despite the fact that sales of Ery products were not transacted at AWP or prices related to AWP, Abbott publicized the Ery AWPs to its customers and was aware of various means in the market for customers to obtain AWP information. (VAC-ERY-SF ¶¶ 18, 37, 41-42, 45). Even after Abbott stopped invoicing at base deal prices, the WACs that it reported were inflated. (VAC-ERY-SF ¶¶ 19-20). Indisputably, the prices Abbott reported to the compendia were not the "best estimate

of the prices generally and currently paid by providers for a drug." *See* 42 C.F.R. § 447.301; *Commonwealth of Massachusetts v. Mylan Laboratories*, 608 F. Supp. 2d 127, 132, 143-44 (D. Mass. 2007).

C. Medicaid's Use of Abbott's Reported Prices

Virtually every state Medicaid program used Abbott's AWPs to set payment levels for Abbott products. *See generally* U.S. Common Brief; (US-C-SF ¶¶ 28-84); (VAC-ERY-SF ¶¶ 56-125). The reimbursement methodology employed by every state Medicaid program included a "lower of" component. (US-C-SF ¶¶ 29-30); (VAC-ERY-SF ¶¶ 66-68). A very common methodology was that a state set its drug reimbursement at the lower of (1) an Estimated Acquisition Cost (EAC), usually based on a published AWP and sometimes based on a published WAC; (2) the Usual & Customary Charge (U&C); (3) a Maximum Allowable Cost (MAC); or (4) Federal Upper Limit (FUL). A limited number of states reimbursed based on the lower of (a) EAC plus a dispensing fee; (b) U&C; (c) the FUL (if any) plus a dispensing fee; (d) the SMAC (if any) plus a dispensing fee; or (e), if applicable, the "DOJ Price" plus a dispensing fee.[3] (US-A-SF ¶¶ 17, 22); (VAC-ERY-SF ¶¶ 66-70). In turn, the states made claims for funding and payment to the Federal Government based on their payments to state providers. *See* U.S. Common Brief; (VAC-ERY-SF ¶¶ 126-132).

Because states incorporate AWPs and/or WACs into their determination of EAC, and EAC is one of several price points considered in determining the "lower of" reimbursement amount, there is no genuine issue that inflated AWPs and/or WACs are materially and causally connected to the submission of claims to the government for the Ery Drugs. Further, Abbott

[3] The "DOJ Price" refers to prices provided in 2000 by the United States Department of Justice and the National Association of Medicaid Fraud Control Units ("NAMFCU") and published by FDB. (US-A-SF ¶ 17).

knew that AWP was used to determine drug payments by third-party payors. (US-A-SF ¶¶ 31-38); (VAC-ERY-SF ¶¶ 16, 36, 43).

D. Abbott's Spread Marketing Conduct

Both within the Pharmaceutical Products Division and elsewhere within Abbott, there was considerable attention paid to the customers' concern about third party reimbursement of Abbott products, including by Medicaid and Medicare. (VAC-ERY-SF ¶¶ 32-51). Abbott worked with other participants in the drug industry, such as wholesalers and retail buying groups, to ensure that information about Abbott's published prices was communicated to customers, allowing them to calculate the spread they would receive upon dispensing Abbott's drug products. (VAC-ERY-SF ¶¶ 37-41). By reporting WACs to the compendia that were significantly above and not related to the prices at which the Ery products were actually sold, Abbott was able to create the reimbursement spread on the Ery products that were important to its customers.

There is abundant evidence that Abbott communicated its AWPs to customers, at least prior to the adoption of a corporate policy in 2004 to stop providing AWP information. (VAC-ERY-SF ¶¶ 42-45, 47). For example, in a 1995 memo concerning various retail buying groups, Bob Rochelle, the Assistant Marketing Manager for Managed Care, discussed various tiered pricing for different Abbott Ery products to chain and retail buying groups (RBGs). A memo describing Abbott's RBG Mail Order Program listed as its objective the influencing of RBG member pharmacies to order Abbott erythromycin products. Attached as part of the circulated packet were templates on Abbott letterhead for the RBGs to use promoting Abbott Ery products to their members based on a comparison between the listed, published AWPs for the products and the price that the RBG member would pay to obtain the product. (VAC-ERY-SF ¶ 45). The

list included AWPs for Ery Filmtabs of $21.92, $104.12 and $189.57 for the 100, 500 and 1000 size packages respectively, while prices listed elsewhere in the packet for the RBG for the same products were $12.95, $62.82 and $121.75, less approximately 10% further discounts off list for high percentage utilization. Ery Tabs, NDC 6304-13, 6304-53 and 6321-13, for different strengths and package sizes, were listed with AWPs of $6.45, $31.29 and $14.30, while the price list for the RBGs listed $23.75, $112.81 and $40.10 for the same products, again with additional discounts noted. *Id*.

Abbott made pricing information, including AWPs, available to the market in many ways, including reporting AWPs to the pricing compendia, or reporting WACs to be calculated into AWPs; discussions between Abbott sales personnel and customers; use of retail stocking sheets that included AWPs; responses to customer bid requests that sought AWP information; and through pharmaceutical wholesalers and group purchasing organizations. (VAC-ERY-SF ¶¶ 47-49). Abbott was aware of the dissemination of AWP information by the intermediaries to Abbott's customers, and used these business relationships to increase customer awareness of spreads. (VAC-ERY-SF ¶ 48). In summary, Abbott:

- controlled the AWPs for its Erythromycin products by adjusting its WAC prices, and prior to 2001, by directly reporting AWPs for these products;
- elected to report its prices to the pricing compendia to ensure its products could be covered by third party programs, including Medicaid, and providers would be reimbursed for these products by these payers;
- reported WAC prices for some Erythromycin products to the compendia that were not reflective of prices generally and currently paid in the marketplace;
- was aware its customers made purchase decisions based on reimbursement

spread; and

- was aware that third party, including Medicaid, reimbursement was based on the WAC and AWP prices that Abbott controlled.

E. Department of Justice and Congressional Investigations

Abbott drastically reduced reported prices for many of its HPD products in 2001 in the midst of years of United States Department of Justice and Congressional investigations. (US-A-SF ¶¶ 56, 58, 66-70). Abbott received its first notice of the United States' investigation on January 22, 1996 – approximately seven months after the relator's initial AWP *qui tam* suit against Abbott was filed – when the Attorney General issued a Civil Investigative Demand (CID) to Abbott seeking information pertaining to price reporting and AWP spreads. (US-A-SF ¶ 111). On October 31, 1997 and August 28, 2000, HHS-OIG issued two subpoenas to Abbott requesting documents and information pertaining to its HPD list price reporting and AWP spread maintenance practices. (US-A-SF ¶ 111).

On October 31, 2000, Abbott's chief executive officer, Miles White, received a letter from Representative Fortney "Pete" Stark which notified Abbott that Congress was investigating its price reporting. In this letter, Congressman Stark asserted that Abbott "intentionally reported inflated prices and has engaged in other improper business practices" and stated his view that "the price manipulation conduct was in no way required by or consistent with existing reimbursement laws or policies." (US-A-SF ¶ 66). He urged Abbott to stop its reporting of inflated prices and asked CEO White to share the letter with Abbott's "Board of Directors and in particular the Board's Corporate Integrity Committee." (US-A-SF ¶ 66)

F. The 2001 Price Reductions

In 2000 and 2001, at the time Abbott received the Stark Letter, Richard Gonzalez served as the vice president and, later, president of Abbott Health Systems. (US-A-SF ¶ 13). After being notified of the 2000 HHS-OIG subpoena, Mr. Gonzalez requested a review and investigation of the disparities between HPD's list prices and contract prices. (US-A-SF ¶ 56, 65, 67). Abbott's HPD subsequently adopted the usual PPD list price formula of WAC plus five percent and adopted a definition of WAC that took into account "chargeback processing after the end sale to a contract provider." (US-A-SF ¶¶ 56-58, 60, 69-70); (VAC-ERY-SF ¶ 11). Abbott essentially conceded the illegitimacy of its reported prices, stating in a draft memo about the price adjustment that "[t]he wide disparity in catalog prices and average market prices as currently configured is not supported by sufficient financial or market factors to survive scrutiny of public opinion." (VAC-ERY-SF ¶ 11).

For the Ery products in PPD, however, Abbott deliberately made no change in its price reporting practices, despite recognizing issues regarding the reported prices for those products. An agenda for a March 2001 meeting involving at least Mike Sellers, General Manager, Contract Marketing, Joe Fiske, and Richard Gonzalez, Abbott's President, concerning the price changes for the HPD products, noted that price adjustments had been discussed with other divisions and that PPD generally reported WAC prices at 5% below List. The document expressly noted discussion about "potential exposure on Ery products which are sold at 40% to 60% below List …." (VAC-ERY-SF ¶ 12). The notes also reflect a concern expressed by Joe Fiske that lower reported prices could have a negative impact on sales volume. *Id*. The reported prices for the Ery products were not changed at this time.

III. ARGUMENT

VAC is moving for partial summary judgment as to liability on its FCA Medicaid claims, specifically falsity of the reported prices, materiality, causation and scienter. In addition, VAC is moving for summary judgment on a number of Abbott's asserted Affirmative Defenses, all loosely based on the notion that Abbott's conduct was not unlawful due to industry practice, government knowledge or acquiescence, or the government's failure to have changed its reimbursement systems. *See* footnote 2, *supra*. None of these defenses is supported by the applicable law. The arguments on these affirmative defenses are set forth in the U.S. Common Brief and are incorporated by reference herein, rather than being repeated.

A. VAC is Entitled to Partial Summary Judgment Regarding the Falsity of Abbott's Reported Prices for the Drugs in this Case.

As noted in the United States' Common Brief, claims presented to the government are false if they are premised on a fraudulent course of conduct that inflated federal payments for Medicaid drug ingredient costs, violating 31 U.S.C. § 3729(a)(1)**.** U.S. Common Brief § II.A. Further, inflated price reporting by Abbott constituted false statements material to false or fraudulent claims, violating 31 U.S.C. § 3729(a)(1)(B).[4] *Id*. As demonstrated below, Abbott reported false prices to publishers and caused the submission of false claims to Medicaid for Abbott's Ery products.

[4] The FCA was recently amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 (FERA), enacted May 20, 2009. Section 3729(a)(1)(B) was formerly § 3729(a)(2), and is applicable to this case by virtue of § 4(f) of FERA, while § 3729(a)(1) of the statute prior to FERA remains applicable here. "The amendments made by this section shall take effect on the date of enactment of the Act and shall apply to conduct on or after the date of enactment, except that (1) subparagraph (B) of section 3729(a)(1), as added by subsection (a)(1), shall take effect as if enacted on June 7, 2008, and apply to all claims under the False Claims Act (31 U.S.C. § 3729, et seq.) that are pending on or after that date …." FERA, § 4(f).

1. Abbott Reported Inflated Prices to the Publishers and Controlled the AWP.

As noted in the common brief, federal Medicaid regulations called for a state Medicaid program to pay the estimated acquisition cost of the drug, along with a reasonable dispensing fee. 42 C.F.R. § 447.301.[5] EAC is defined in the Medicaid regulations as the agency's "best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." 42 C.F.R. § 447.301. This definition was in place throughout the time period covered by this complaint, without change, and it was incorporated into many of the State regulations concerning reimbursement also. (VAC-ERY-SF ¶¶ 56-57).

Throughout the claims period, Abbott reported inflated prices for the Ery complaint drugs to all three Publishers. (US-A-SF ¶¶ 14-24); (VAC-ERY-SF ¶¶ 7-8, 45, 51). These prices were not predictably related to the estimated acquisition costs for Abbott drugs. Specifically, the Pharmaceutical Products Division deviated from its own usual practice and did not actually bill wholesalers at so-called WAC prices, which were the prices reported to the compendia and sometimes provided directly to Medicaid programs. Abbott essentially admits that these prices had no relationship to the prices actually charged by Abbott PPD to its customers for the Ery drugs at issue. (VAC-ERY-SF ¶¶ 7-10, 43). As discussed below, the inflated list prices were the basis from which the AWPs were determined by the Publishers and, consequently, were the prices driving reimbursement rates by government payors.

Abbott's price reductions on HPD drugs after Congressional inquiries and media scrutiny, (US-A-SF ¶ 58), as well as its price reporting for PPD drugs, knowing how the

[5] The citations herein are to the federal regulations governing Medicaid drug payments that were in effect prior to October 1, 2007. Most of the claims at issue arose before that date.

compendia calculated AWPs, reveal that Abbott controlled the AWPs at issue. (VAC-ERY-SF ¶¶ 7, 14, 43). Despite scripted denials that Abbott was responsible for published AWPs, numerous employees testified that they were fully aware of the formula the publishers applied to Abbott's reported prices to churn out AWPs and that they understood that changing the prices Abbott reported would have led to changed AWPs being published. (VAC-ERY-SF ¶ 14). As this Court has determined in several contexts, this knowledge of the calculations undertaken by the pricing compendia, coupled with control of the prices from which these calculations were undertaken, constitutes control of the published AWPs. *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 61 (D. Mass. 2007) (reviewing evidence to determine that manufacturers could affect and, at times, fully control AWPs). *See also Mass. v. Mylan Labs.*, *supra*, 608 F. Supp. 2d at 145-46. Additionally, Abbott's conduct in maintaining the inflated published prices for its Ery drugs in 2001 reflects a deliberate decision to continue defrauding the Medicaid program. (VAC-ERY-SF ¶ 12).

2. Abbott's Actual Sales Prices Were a Fraction of the Reported List Prices, Creating Mega-Spreads.

During the course of this litigation, VAC received actual sales transaction data from Abbott for the Ery Drugs. Exhibits 1-86 to the Declaration of Ian Dew ("Dew Declaration") show the indirect pharmacy average prices for each of the NDCs at issue in this action. The exhibits are comprised of tables and graphs showing the differential or spread between the AWP and the average sales price for each drug in this case. As shown by the data reflected in the tables and graphs, the spreads on the drugs at issue were generally in the range of 60% to 300%. *See In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F. Supp. 2d 20, 31, 40 (D. Mass. 2007). As discussed further below, Abbott's creation and maintenance of mega-spreads on these drugs rendered false the payment claims for these drugs.

3. Abbott's Reporting of the Pricing Information to the Publishers Constituted False Statements and Rendered the Claims False.

Attached as exhibits to the Thomas Declaration are documents transmitting false and fraudulent pricing information to the Publishers used by Medicaid and Medicare to set payment levels for Abbott's drugs. (VAC-ERY-SF ¶ 6) (including historical list of Abbott communications regarding prices to Red Book and price verification communications between 1995 and 2000). Abbott employees also testified that Abbott reported price information to the compendia (VAC-ERY-SF ¶¶ 6, 14-15). Based on the plain meaning definition of AWP adopted in these matters,[6] this Court has held that AWP and WAC prices that have no relationship to the actual prices paid by the defendants' customers are false. *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 103, 105-08 (D. Mass. 2007); *In re Pharm. Indus. Average Wholesale Price Litig.*, 520 F. Supp. 2d 267, 270 (D. Mass. 2008). Abbott has conceded that the reported prices on the Ery Drugs did not reflect the prices generally and currently paid by the overwhelming majority of its customers, contrary to the general practice of PPD. (VAC-ERY-SF ¶¶ 7-9, 12, 15, 17-18). These transmittals are false statements about the price of Abbott's drugs. *See* U.S. Common Brief. Based on the above facts and legal analysis both in this brief and in the common brief, the government's use of these false or fraudulent prices to set payment levels made Abbott's statements to the Publishers material to false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(1)(B).

It is significant that this Court's prior rulings are completely consistent with government policies that sought to pay for drug ingredient costs in the Medicaid and Medicare programs at or

[6] *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 277, 287 (D. Mass 2006).

around estimated acquisition cost.[7] *See* U.S. Common Brief at § III(B)(1). As noted in the common brief and the statement of facts for the common brief, state Medicaid programs used Abbott's AWPs or WACs to set reimbursement levels for Abbott's drugs. *See* U.S. Common Brief at § III(B)(2), (US-C-SF ¶¶ 25-84); (VAC-ERY-SF ¶¶ 62-125). Claims reimbursed off of Abbott's inflated AWPs or WACs and payments which would have been lower had Abbott reported more accurate prices were false and/or fraudulent, in violation of 31 U.S.C. § 3729(a)(1). *See* U.S. Common Brief at § III(A). The fraud underlying the claims is material for the same reasons the false statements are material.

B. VAC is Entitled to Partial Summary Judgment Regarding Materiality and Causation for False Claims to the Medicaid Program.

Materiality and causation are addressed together because the factual premises are intertwined. As set forth in the Common Brief, materiality is defined as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property. *See* U.S. Common Brief § III(C). *See also Mass. v. Mylan*, 608 F. Supp. 2d 127, 145, 153 (D. Mass. 2008); *United States ex rel. Longhi v. United States*, 2009 WL 1959259 at *8 (5th Cir. 2009) ("All that is required under the test for materiality, therefore, is that the false or fraudulent statements have the potential to influence the government's decisions.")[8]

[7] This Court has recognized that defendants' claim that "they have *carte blanche* to publish sky-high prices unmoored from the acquisition costs of providers leads to absurd results." *See State of California ex. rel. Ven-A-Care v. Abbott*, 478 F. Supp. 2d 164, 173 (D. Mass. 2007). The Court has further noted that drug prices which "cross any reasonably drawn line between estimates which reasonably reflect prices paid by providers and estimates which are so grossly inflated when compared to actual acquisition costs … are by their very nature fraudulent." *Id*. at 174.

[8] In addition, just recently, Congress codified this materiality standard in FERA, 31 U.S.C. § 3729(b)(4), Pub. L. No. 111-21, § 4(b)(4).

The Myers and Stauffer summaries show how these reported prices were used by government agencies to pay for Abbott's drugs. *See* Henderson Declaration attached to the U.S. Common Brief (Henderson Common Decl.) (US-C-SF ¶¶ 36-84); (VAC-ERY-SF ¶¶ 62-125). As shown in these summaries, the manufacturer's AWP – discounted by a modest percentage – was used as a proxy for estimated acquisition cost by the vast majority of states during the claims period. (Henderson Common Decl. Ex. 24). The United States has further explained how the federal government then shares in the payments to providers for drug ingredient costs. (US-C-SF ¶¶ 85-91); (VAC-ERY-SF ¶¶ 126-132).

Abbott PPD employees have acknowledged their understanding that PPD utilized special "base deal" prices for the Ery products, which were not disclosed to pricing compendia or Medicaid programs, nor were they ascertainable from Abbott's reported WACs or published AWPs. (VAC-ERY-SF ¶¶ 8, 12, 17-18).

Under applicable case law, it is clear that Abbott caused false claims to be presented. The test is set forth in *United States ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co.*, 2003 WL 22048255, at *4 (D. Mass. Aug. 22, 2003). First, the court should examine whether a defendant's conduct was a "substantial factor" in causing the presentation of false claims to the Medicaid program. Second, the court needs to examine whether the submission of false Medicaid claims by providers was a foreseeable consequence of Abbott's conduct.

By reporting false prices to the compendia used by state Medicaid programs to estimate drug ingredient costs, Abbott caused providers to submit false or fraudulent claims for Medicaid reimbursement on Abbott's drugs. The Medicaid payment data confirms that the Medicaid program (1) paid for the Abbott NDCs at issue and (2) at levels pegged to or affected by the inflated AWPs. (US-C-SF ¶¶ 36-85, 116-120, 150, 153); (VAC-ERY-SF ¶¶ 62-70). Where

claims were actually paid on a price other than the published AWP or WAC, the damages calculation only attributes damages to Abbott if an AWP based on prices generally and currently paid would have been the lowest price in the "lesser of" algorithm. (VAC-ERY-SF ¶¶ 52-54, 66-70).

Thus, to the extent Abbott argues that payment levels may have been affected by a state MAC or another price other than its reported AWPs or WAC, that is only a damages issue, to be resolved at trial. Because of the "lesser of" formulas used by virtually all Medicaid agencies, it is not an issue pertinent to determining Abbott's liability. *Mylan*, 608 F. Supp. 2d at147 (liability issue is not about payment of claims); *see also United States ex rel. Fago v. M&T Mortg. Corp.*, 518 F. Supp. 2d 108 (D.D.C. 2007) (distinguishing between FCA causation as a matter of liability and causation as an FCA damages issue).

This Court has already determined that the reporting of prices not reflective of actual transaction prices is sufficient to cause the presentment of inflated provider claims where reimbursement is calculated based on those prices. *See State of California ex. rel. Ven-A-Care v. Abbott*, 478 F. Supp. 2d at 175; *Mass. v. Mylan Labs.*, 608 F. Supp. 2d 127, 145 (D. Mass. 2008) (where drug manufacturers report inflated prices to Medicaid programs through the pricing compendia, knowing that providers will be reimbursed based on those prices, defendants are chargeable with causing false claims to be submitted). Since VAC has demonstrated that (1) Abbott reported or caused the calculation of false AWPs to the compendia for the Ery Drugs; (2) claims for payment for Abbott's Ery Drugs were presented to state Medicaid programs and, ultimately, the United States; and (3) the majority of states used Abbott's false AWPs in their algorithms seeking the "lesser of" price to be paid, to estimate acquisition cost for its drugs, VAC has established that Abbott caused false claims to be presented.

C. VAC is Entitled to Partial Summary Judgment That Abbott's Conduct Related to the Submission of False Claims was Knowing or, at a Minimum, in Reckless Disregard of the Truth or Falsity of the Information or Claim.

1. The evidence demonstrates Abbott acted knowingly.

For purposes of the FCA, "knowledge" that a statement or document was false or fraudulent means that the defendant: (1) had actual knowledge that the claim was false; (2) acted in deliberate ignorance of the truth or falsity of the claim; or (3) acted in reckless disregard of the truth or falsity of the claim. No specific intent to defraud is required. 31 U.S.C. § 3729(b);[9] *United States ex rel Loughren v. Unumprovident Corp.*, 2008 WL 4280133 at *3 (D. Mass. Sept. 15, 2008); *Longhi*, 2009 WL 1959259 at *7; *United States ex rel. Quirk v. Madonna Towers, Inc.*, 278 F.3d 765, 767 (8th Cir. 2002). Based on undisputed evidence, it is apparent that Abbott had the requisite knowledge about the falsity of its conduct and the claims at issue.

Abbott was party to a Rebate Agreement with the United States, and from 1991 through 2008, was enrolled as a provider in the Medicare and Medicaid program, as well. (US-A-SF ¶¶ 4-12). As this Court noted:

> having entered into the rebate agreements, [a defendant is] required, as a matter of law, to familiarize [itself] with the legal requirements, standards and procedures of the Medicaid program, *Heckler v. Community Health Servs.*, 467 U.S. 51, 63-65 (1984). These include the procedures and legal requirements applicable to reimbursements. *United States v. Mackby*, 261 F.3d 821, 828 (9th Cir.2001). [A defendant is] required to know that the Commonwealth's EAC was 'the agency's best estimate of the price generally and currently paid by providers.'

[9] Plainly, therefore, lack of evidence of intent to defraud or even affirmative evidence showing no intent to defraud is not a defense, as long as plaintiff proves that defendants submitted false claims or made false statements with knowledge of the falsity or reckless indifference or deliberate ignorance of the falsity. *See United States ex rel. Hefner v. Hackensack University Medical Center*, 2005 U.S. Dist. LEXIS 36427 at *25 (D.N.J. 2005) (lack of evidence of specific intent not significant because no specific intent to defraud is required); *In re Cardiac Devices Qui Tam Litigation*, 221 F.R.D. 318, 339 (D. Conn. 2004) (same).

Mylan, 608 F. Supp. 2d at 154. Abbott had an obligation to familiarize itself with the legal requirements, standards and procedures of the Medicaid program. Ignorance of the law is no defense to its false price reporting and the resulting damage to the government programs; indeed, it constitutes affirmative evidence of Abbott's deliberate ignorance of its obligations as a direct participant in, and as a manufacturer whose products are reimbursed under, the Medicaid program. Deliberate ignorance of the truth or falsity of claims meets the FCA's "knowledge" requirement. *Id*. at 154-155.

a. Abbott's Knowledge By Virtue of Its Own Participation As a Provider and a Partner of Providers

The undisputed evidence shows that Abbott knew, or was deliberately ignorant or reckless about, the falsity of its price reporting to the Publishers and the effect of its conduct on the Medicaid program. Within Abbott, there was a business segment that operated as a provider and actually submitted claims for drug reimbursement under Medicaid. Home Infusion's business model involved, in part, collecting or sharing in the reimbursement spreads on the Abbott products in exchange for the provision of Abbott products, and for the provision of services, at no separate cost. (US-A-SF ¶¶ 134-141). Abbott concedes that Home Infusion employees within HPD were familiar with how Medicaid reimbursed; those reimbursement employees directly submitted claims to Medicaid on behalf of Abbott's own pharmacies and under service arrangements with its partners. (US-A-SF ¶ 132). There was substantial overlap and migration of employees between HPD and PPD. (VAC-ERY-SF ¶¶ 34-36). For example, the PPD Supervisor of Chargebacks and Memberships, and at least one PPD Contract Analyst, had experience in Abbott's Home Infusion business. (VAC-ERY-SF ¶ 34).

By virtue of the operation of this business, Abbott had actual knowledge of the effect of its price reporting on Medicaid. (US-A-SF ¶¶ 134-141). Indeed, its business model depended

upon high spreads from third-party payors, including Medicare and Medicaid, sufficient to cover Abbott's costs and those of its Home Infusion partners, while providing for profit. (US-A-SF ¶¶ 146-147).

b. Abbott Knew or Was Reckless or Deliberately Ignorant About the Effect of Its False Pricing Conduct on Claims.

It is also undisputed that the list prices set and reported by PPD for the Ery products (1) were rarely paid and were prices at which Abbott sold less than five (5) percent of its products; (2) did not adjust for decreasing or flat average transaction prices; and (3) were significantly higher than prices generally and currently paid for Abbott's Ery Drugs in the marketplace. (VAC-ERY-SF ¶¶ 7-9, 17-18). Unlike in the *Mylan* case, there is no sworn testimony creating an issue of fact that Abbott PPD believed the prices it reported to be invoice prices. *Mylan*, 608 F. Supp. 2d at 154. Quite to the contrary, Abbott employees testified that they knew that the base deal prices were almost always lower than published prices.[10] The charts showing spreads on each NDC on the complaint confirm this testimony. (VAC-ERY-SF ¶¶ 18, 51); Dew Decl., Exhs. 1-86.

Abbott had a Medicare Working Group, which had two PPD representatives. (VAC-ERY-SF ¶¶ 22-25). Abbott's Medicare Working Group kept abreast of reimbursement issues and used its status to participate as an industry leader on certain initiatives, including legislative initiatives. It also monitored legislation for changes in reimbursement. (VAC-ERY-SF ¶¶ 22-25). Among the discussions had by the Medicare Working Group, when PPD members Don Buell and Don Conway were both present, there was a discussion of a possible pricing change by some state programs for Lupron, to acquisition cost. The notes from the meeting indicate that

[10] Abbott testified that it reported its highest prices to the Publishers and that the only prices it would make public were its highest prices. (US-A-SF ¶ 84); (VAC-ERY-SF ¶¶ 18, 51).

this would present a problem for Abbott because it would take all the providers' profit out of prescribing Lupron and would result in providers instead dispensing the lower cost Zoladex product. (VAC-ERY-SF ¶ 25).

Finally, during the relevant period, Abbott's joint venture with Takeda Pharmaceutical Company, TAP Pharmaceuticals, was the subject of a criminal and civil probe that resulted in a plea agreement and civil settlement with the United States and numerous states totaling nearly $850 million. Part of the civil settlement resolved allegations that TAP manipulated prices and marketed the spread. (US-A-SF ¶ 131). During the period relevant to this case, Abbott was aware of TAP's legal exposure, in part because, as a joint venturer, it directly entered into a related side agreement with the United States confirming Abbott's agreement with the resolution of the TAP matter. (US-A-SF ¶¶ 130-131). Abbott's in-house lawyers, who had exclusive domain within Abbott over Medicare and Medicaid compliance, worked with TAP Pharmaceuticals on its AWP issues and problems. (US-A-SF ¶ 130).

2. At a Minimum, Abbott Acted with Reckless Disregard as to the Truth or Falsity of Its Pricing and the Impact of Its Pricing on Government Reimbursement.

Given Abbott's knowledge of its special method of price reporting for Ery drugs in PPD, there is no genuine issue of disputed fact that, at a minimum, Abbott acted with reckless disregard of the truth or falsity of these prices. While there is ample evidence that Abbott acted with actual knowledge, even viewing Abbott's own testimony in the light most favorable to it, there is no dispute that Abbott PPD employees acted with reckless disregard of the truth or falsity of their prices when setting and reporting list price to Publishers.

The undisputed facts are that Abbott's price reporting, during the relevant years for the drugs at issue, evinces at least a reckless disregard for the Medicaid reimbursement

requirements. There is no evidence of an effort by PPD to report prices for the Ery drugs that reflected prices generally and currently paid by its customers or that would have allowed Medicaid programs to estimate acquisition costs. *See Mass. v. Mylan Labs.*, 608 F. Supp. 2d. 127, 144 (D. Mass. 2008) ("Given that EAC was calculated based on WAC [in Massachusetts], understanding WAC to be what wholesalers actually paid to acquire the drugs furthers the purpose. Understanding WAC as a mere list price does not.").

Abbott's employees performed their duties not in a vacuum, but in the full purview of Abbott as a corporate actor. Abbott PPD's conduct in pricing its Ery drugs was not in line with Abbott's regular PPD pricing conduct. (VAC-ERY-SF ¶¶ 7-8). The PPD employees who reported prices for the Ery products had access to the bid pricing schedules by which business was actually transacted. (VAC-ERY-SF ¶ 10). They also knew that Abbott's reported prices were used in government reimbursement (VAC-ERY-SF ¶ 15), and that customers were interested in reported prices because that was the basis on which they were reimbursed. (VAC-ERY-SF ¶¶ 15-16). Internally, Abbott calculated its average sales prices on at least a monthly basis, based on WAC sales less rebates, discounts and other billing adjustments. (VAC-ERY-SF ¶ 21). When Abbott decided to drastically lower its reported prices for many HPD products in 2001, in conjunction with government investigations (VAC-ERY-SF ¶ 11), Abbott's PPD managers participated in discussions about whether to change the price reporting for Ery products also. (VAC-ERY-SF ¶ 12). Despite recognizing some "exposure" on Ery products that were being sold at 40% to 60% below the reported prices (VAC-ERY-SF ¶ 12), Abbott decided to continue reporting those prices and have Medicaid continue to reimburse providers at those inflated prices.

In the *Longhi* case, where the defendants similarly defended their submission of false claims as inadvertence; the Fifth Circuit upheld the district court's summary judgment determination that the defendant acted, at a minimum, with reckless disregard in view of the defendant's distortion of its participation qualifications in the federal grant program which paid money to defendant as a grant recipient. *Longhi*, 2009 WL 1959259 at *10 (5th Cir. 2009); *see also United States v. Krizek*, 111 F.3d 934, 941-942 (D.C. Cir. 1997) (equating the FCA reckless disregard standard to aggravated gross-negligence, and finding reckless disregard when the wife completed claims for payment with little or no factual basis, and the physician "utterly failed" to review the information before its submission to Medicare and Medicaid.)

For these reasons, Abbott's undisputed conduct amounts to at least reckless disregard, and summary judgment is appropriate as to the FCA scienter element for that reason alone.

D. Abbott Cannot Assert A Government Knowledge Defense.

As set forth in the U.S. Common Brief, this Court should rule that government knowledge, to the extent it is relevant in this case, is limited to its effect on a particular defendant's scienter. *See* U.S. Common Brief § III(C), incorporated by reference herein. Abbott asserts various defenses tacitly premised on government knowledge.[11] This Court should enter

[11] VAC moves for summary judgment as to the following Affirmative Defenses: Good faith, established industry practice (Seventh Affirmative Defense); laches, estoppel and waiver (Eleventh); Abbott's actions were not proximate cause of any injury (Thirteenth); Abbott did not make any false statements to the plaintiff, or if false or misleading, Abbott had no reasonable grounds to believe and did not believe that the statements were false or misleading (Fifteenth); *in pari delicto* or unclean hands (Nineteenth); Plaintiff's failure to follow state and federal regulatory obligation to set reimbursement rate at appropriate Estimated Acquisition Cost (Twentieth); failure to mitigate damages, plaintiff would be unjustly enriched, consent or ratification to extent government paid for drug products after initial complaint filing in 1998 (Twenty-fifth); Abbott's conduct was not material to any alleged injuries suffered by plaintiff (Thirty-First); no reliance by United States or states (Thirty-Second); plaintiff knew and was aware the AWP was not an actual average of wholesale prices or the actual acquisition cost of

summary judgment in favor of VAC on the applicability of a government knowledge-based defense to the issue of scienter, falsity or any related affirmative defenses because there is no genuine issue of material fact; Abbott cannot meet the elements of any government knowledge-based defenses.

1. Abbott cannot fulfill the prerequisites for a government knowledge-based defense to FCA falsity or scienter.

In the common brief, the United States argues that government knowledge in an FCA case is relevant only to scienter. *See* U.S. Common Brief § IV(C).[12] The principle that a government knowledge defense should be strictly construed is consistent with numerous other limitations on a government contractor's potential liability. Notably, the government's "inspection and acceptance of a product do not absolve a contractor from liability for fraud under the FCA." *Varljen v. Cleveland Gear Co.*, 250 F.3d 426, 430 (6th Cir. 2001); *United States v.*

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drugs (Thirty-Sixth); and contributory or comparative fault because of plaintiff's own conduct or failures (Thirty-Ninth).

[12] Despite the repeal of the "government knowledge" jurisdictional bar, the term "government knowledge" continues to be used, but for an entirely different set of circumstances:

> The inaptly-named "government knowledge defense' captures the understanding that the FCA reaches only the "knowing presentation of what is known to be false." Where the government and a contractor have been working together, albeit outside the written provisions of the contract, to reach a common solution to a problem, no claim arises. The government's knowledge and acquiescence in its contractor's actions in many cases is "highly relevant" to show that the contractor did not submit payment claims in deliberate ignorance or reckless disregard of their truth or falsity.

United States v. Southland Mgmt. Corp., 326 F.3d 669, 682 (5th Cir. 2003) (en banc) (Jones, J., specially concurring, joined by Smith, Barksdale, DeMoss, Clement, JJ.) (footnotes and extensive internal citations omitted, emphasis added). Accordingly, the "government knowledge" defense is a misnomer and is "inaptly named because it is not a statutory defense to FCA liability but a means by which the defendant can rebut the government's assertion of the 'knowing' presentation of a false claim." *Id.* at 682 n.26 (Jones, J., specially concurring).

Aerodex, Inc., 469 F.2d 1003, 1009 (5th Cir. 1972). Further, a party can be liable for causing another entity to submit a false claim even if the claimant did not know the claim was false. *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243-44 (3d Cir. 2004). Nor does a contractor escape liability under the FCA by demonstrating that it expected an inflated claim to be discovered and corrected by a scheduled audit. *United States ex rel. A+ Homecare, Inc. v. Medshares Mgt. Group, Inc.*, 400 F.3d 428, 447 (6th Cir. 2005) ("party cannot file a knowingly false claim on the assumption that the fiscal intermediary will correctly calculate the value in the review process").

As further set forth in the United States' brief, to succeed on a government knowledge-based scienter argument, Abbott must meet three criteria: a) that it fully informed the appropriate government officials of the actual facts and the precise nature of the deviance between the Abbott's reported prices and the actual prices generally and currently paid by providers for those products; b) that the government affirmatively approved of the alleged wrongful price reporting conduct; and c) that Abbott's list price setting and reporting conduct in fact was premised on an understanding that the government had approved of the conduct at issue. *See* U.S. Common Brief § IV(C). The evidence shows Abbott cannot meet any of these elements.

a. Abbott Never Fully Informed Government Officials of the Actual Facts.

To succeed on a government knowledge-based scienter argument, Abbott must show that the "government [possessed] knowledge of the *actual true facts* of the claim, not simply knowledge that the claim is generally false." *Mylan*, 608 F. Supp. 2d at 148 (emphasis added). Abbott admitted that it never fully informed the appropriate government officials of the *actual* facts or particulars of the precise nature of the deviance between its reported prices and its contract or marketplace prices. (US-A-SF ¶¶ 105-106, 108, 112); (VAC-ERY-SF ¶ 8). Indeed,

it was a clear company policy to not disclose the base deal prices at which Abbott PPD transacted business for the Ery products. *Id*.

Moreover, it is ridiculous to expect the government to have examined every Abbott product for price discrepancies, particularly where, as here, other products sold by the same division of Abbott had totally different price reporting patterns. (VAC-ERY-SF ¶¶ 7-8). Even a cursory examination of the spread calculations submitted as exhibits to the Dew Declaration show the knowledge gap between having a general perception that published AWPs are not an actual average of wholesale prices versus actually knowing the prices at which drugs were acquired or the amount of the inflation in the published prices. There were wide variations in both the dollar amount and the percentage calculation of spread for any given NDC (*See, e.g.*, Dew Exhs. 1, 10, and 15, showing, respectively, dollar spread ranges for specific NDCs of $7.95 - $14.68 and percentage spreads from 60.57% to 153.71%; $11.62 - $18.52 and 98.91% to 255.55%; $5.72 - $8.00 and 165.95% to 413.78%). Within a given drug code, the percentage spread often varied significantly for different package sizes. (*See, e.g.*, Dew Exhs. 29-31, for NDCs 00074-6346-19, -20, and -38, respectively, showing spread percent ranges from 122.05% - 179.22%; 78.24% - 172.42%; 74.41% - 125.65%). Even at a given point in time, the spread percentage could vary markedly within a drug code. (Again, looking at NDC 00074-6346-19, -20, and -38, depicted on Dew Exhs. 29-31, the percentage spread on the different size packages ranged from 134.04% to 132.76% to 88.79% in 1996 quarter 1, from 126.15% to 143.13% to 74.41% in 1998 quarter 1, and from 122.58% to 170.80% to 78.30% in 2002 quarter 1). (VAC-ERY-SF ¶ 54). Additionally, it is no defense to say that the government had AMP prices, because those prices were not disclosed to the State Medicaid programs and the prices were kept confidential. (VAC-ERY-SF ¶¶ 139-156).

b. The Government Never Approved of Abbott's Wrongful Price Reporting.

Abbott did not seek or receive approval for its list price setting or price reporting conduct from the United States or any state, and cannot rely upon a government knowledge defense as a result. There were no explicit directions from the government that Abbott relied upon. *See United States ex rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d 284, 288-89 (4th Cir. 2002); *United States ex rel. Werner v. Fuentez Systems Concepts, Inc.*, 319 F. Supp. 2d 682, 685 (N.D. W.V. 2004); *United States ex rel. Stebner v. Stewart & Stephenson Servs.*, 144 Fed. Appx. 389, 394 (5th Cir. 2005); *United States ex rel. Durcholz v. FKW*, 189 F.3d 542, 545 (7th Cir. 1999); *United States ex rel. Ven-A-Care v. Abbott Laboratories*, 254 F.R.D. 35, 42-43 (D. Mass. 2008).

In the scores of cases where defendants argued, like defendants here, to the effect that the government agency approved or ratified the alleged false claims or statements, defendants introduced factual evidence to demonstrate their interaction with appropriate officials about the particular issue at hand *and* the government agency's affirmative acceptance of the later-alleged misconduct. Indeed, in a similar case brought under a state consumer fraud statute and common law fraud involving prices for Lupron, the trial judge granted plaintiffs' motions *in limine* precluding defendants from introducing evidence of insurer knowledge or government knowledge about AWPs precisely because defendants had no evidence to show that the government or insurers acknowledged or approved of the spreads between market and reported prices. *Walker v. TAP Pharmaceuticals Products, Inc.*, CPM L 682-01, Mem. of Decision dated May 9, 2005 (Superior Court of New Jersey).

Moreover, in these cases, there is a huge body of evidence showing that the federal government was concerned about the high reported prices and was searching initially to

understand the problem and then for means to bring payment levels down. Indeed, this Court has characterized the government during the relevant time period as the "government pit bull." *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 41, 44 (D. Mass. 2007). Moreover, as this Court has already determined, the OIG's release of the Pharmaceutical Guidelines in 2003 warning that setting and marketing high AWPs could constitute fraudulent conduct violative of federal anti-kickback statutes, was definitive evidence that the federal government did not acquiesce in defendants' inflated price reports and spread marketing. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 95 (D. Mass. 2007) ("[these guidelines] defeat any notion that the federal government's failure to change the AWP pricing benchmark signaled acquiescence in spread-marketing or the reporting of mega-spreads."); (VAC-ERY-SF ¶¶ 137-138). *See also In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 277, 285 (D. Mass. 2006) ("The weight of the legislative history reflects congressional intent to have the AWP moored to actual wholesale pricing, and a nagging concern that AWP was no longer a reasonable price.")

Furthermore, at this point in the case, Abbott's (and other defendants') discovery directed at the federal government has been extensive – yet they have unearthed no evidence of government approval of their conduct. In response to defendants' requests, the government has produced hundreds of thousands of pages of documents. A cornucopia of investigative reports is publicly available and defendants have shown the Court a full collection over three decades. With their comprehensive document collection, defendants have deposed a litany of current or former government employees from CMS (and its predecessor, HCFA), as well as State Medicaid agencies.

Notwithstanding this far-reaching discovery effort, defendants have adduced *no evidence* that CMS ordered, approved or ratified defendants' submission of AWP and WAC prices that bore no rational relationship to the actual prices at which defendants sold their products, that did not constitute good faith estimates of the average wholesale price or wholesaler acquisition cost of these products, that did not bear a consistent and ascertainable relationship to any actual market prices and that provided no means whatsoever for CMS or the State Medicaid programs to calculate an estimated acquisition cost of the drugs.

Not one memo, conversation or publication from CMS directs or orders defendants to submit and maintain random and inflated AWPs or WACs or approves or ratifies the inflated price submissions. There is a complete and total absence of the type of evidence necessary to muster a government approval defense. *United States ex rel. Durcholz v. FKW*, 189 F.3d at 545 (no FCA liability if government "knows and approves of the particulars of a claim"); *United States ex rel. Costner v. URS Consultants, Inc.*, 317 F.3d 883, 886-87 (8th Cir. 2003) (EPA was informed of operational problems but approved monthly payments, did not consider difficulties to be contractual violations and worked with defendants to resolve problems); *United States ex rel. Butler v. Hughes Helicopter*, 71 F.3d 321, 328 (9th Cir. 1995) (non complying tests were known to and approved by Army).

Legally, knowledge and inaction do not equal government approval that insulates a government contractor from liability for submitting false claims. The defense turns on some affirmative act of approval by the government agency. *See In re Pharmaceutical Industry AWP Litigation*, 263 F. Supp. 2d 172, 187 (D. Mass. 2003) ("the fact that Congress has failed to disturb the widespread practice on the part of pharmaceutical companies of grossly overstating their AWPs cannot be read as a clear and manifest intention to grant immunity from state

regulation of such fraudulent practices."); *In re Lupron Mktg. & Sales Practices*, 295 F. Supp. 2d 148, 168 n. 19 (D. Mass. 2003) ("recognition on the part of government regulators of inefficiencies in the administration of Medicare does not, as defendants contend, amount to condonation of fraudulent conduct"); *Walker v. TAP Pharmaceutical Products, Inc.*, *supra* (knowledge of acquisition costs and continuing to utilize AWP reimbursement system does not demonstrate acceptance or approval of spread system). Indeed, generally, failure of a legislature or agency to take action cannot support an inference of any particular legislative intent because many factors can explain legislative inaction. *See, e.g.*, *United States v. Craft*, 535 U.S. 274, 287 (2002) ("congressional inaction lacks persuasive significance because several equally tenable inferences may be drawn from such inaction"); *Arnold Tours, Inc. v. Camp*, 472 F.2d 427, 437 (1st Cir. 1992) ("Congressional inaction frequently betokens unawareness, preoccupation or paralysis").

c. Abbott Never Acted Upon Any Government Approval In Setting and Reporting Its List Prices.

Finally, Abbott testified that its price reporting was in no way dependent on government approval. (US-A-SF ¶¶ 105-106). The testimony of Rule 30(b)(6) corporate designees showed that Abbott: a) never sought any guidance from the United States concerning its list price reporting conduct; b) never sought approval from the government for its reporting of list prices; c) never informed the government, or any state other than Texas, of its prices currently and generally paid or charged in the marketplace for its Ery Drugs; and, d) never relied upon any information pertaining to Medicaid to inform its list price setting or reporting conduct. (US-A-SF ¶ 123); (VAC-ERY-SF ¶¶ 28-30).

Through its Affirmative Defenses, its employees' testimony and its expert reports, Abbott argues that it was government policy to pay inflated reimbursement. VAC, like the United

States, disputes this argument, but assuming, *arguendo*, it was true, Abbott admitted that Medicaid reimbursement, and/or cross-subsidization of Medicaid reimbursed dispensing fees and provider costs, never influenced or impacted Abbott's list pricing decisions. (US-A-SF ¶ 40). Therefore, even the alleged government policy did not drive Abbott's conduct. Accordingly, there is no genuine issue of disputed fact, and for this reason, the United States is entitled to summary judgment on Abbott's purported defense of government knowledge.

E. VAC is Entitled to Partial Summary Judgment on Certain of Abbott's Affirmative Defenses.

Several of Abbott's affirmative defenses are variations of a "government knowledge" defense, or a "government's fault" defense, that are legally unsupportable. These arguments are addressed in the U.S. Common Brief § IV(C). VAC respectfully requests that the Court grant summary judgment on the affirmative defenses delineated in footnote 2, basically variations of the following: release, laches, estoppel and waiver, a failure to mitigate damages, ratification, government knowledge, contributory or comparative fault, or unclean hands. Additionally, VAC seeks summary judgment on Abbott's asserted defenses pertaining to proximate cause (Thirteenth), reliance (Thirty-Second), and materiality (Thirty-First) based on the arguments presented on those issues under the False Claims Act.

IV. CONCLUSION

For the reasons stated above, VAC requests that the Court grant it summary judgment as to liability, specifically on the elements of falsity, materiality, causation and scienter on its FCA Medicaid claims, and summary judgment on the enumerated Affirmative Defenses.

Respectfully submitted,

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I hereby certify that I have this day caused an electronic copy of the above **MEMORANDUM IN SUPPORT OF PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT** to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: August 28, 2009

/s/ Susan Schneider Thomas .
Susan Schneider Thomas